Patient Information Leaflet for ASLS Resorbable Sleeve

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

This implant is used for the operative treatment and stabilisation of fractures in the tibia (shin bone). Your doctor will choose the appropriate implant to meet your needs. As with any medical treatment, individual results may vary.

Implant Material

This implant contains 70:30 poly(L-lactide-co-D,L-lactide).

This material consists of a co-polymer produced only from lactide monomers. It retains stability for 12 weeks, and then it is gradually absorbed by your body over a number of years.

Information for Safe Use

There is nothing for you to do to ensure safe use of this device. You should follow your doctor's advice after surgery. Discuss any questions, concerns, or potential side effects with your doctor.

Due to the nature of the polymer material, i.e. intrinsically non-metallic, non-conductive and non-magnetic, no influence in a magnetic field must be expected.
For details on MRI information for the used nails and locking bolts/screws please refer to the specific labeling of these devices.

If you do need an MRI, you should let your doctor know about any previous surgeries.

Possible Side Effects / Risks

Your doctor will provide information about the side effects of your operation. All operations have risks. The risk of a serious issue is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns.

Possible risks may include:

- Problems resulting from anesthesia (numb sensation in certain areas of the body or induce sleep) and patient positioning (e.g., sickness, vomiting, dental injuries, neurological impairments, etc.)
- Thrombosis (blood clots blocking your blood vessels)
- Embolism (blocked artery caused by a blood clot or an air bubble)
- Infection

- Excessive bleeding
- Abnormal scar formation
- Functional impairment of the musculoskeletal system (The ability to perform certain body movements may be restricted)
- Sudeck's disease
- Allergy/hypersensitivity reactions (Allergic Reaction)
- Side effects associated with hardware prominence
- Malunion (Incorrect alignment of the device)
- Non-union (A gap in the joint or bone)

These risks may require additional operations or treatments. This list does not include all risks. Your doctor can further explain the risks of your operation.

Expected Implant Lifetime and Follow Up

Your implant retains its stability during the first bone healing phase (approximately 12 weeks). Afterwards, the device will be absorbed by your body within approximately 2 years. The resorption rate varies from patient to patient.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your soft tissue reattachment implant, please speak with your medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com and the Therapeutic Goods Administration at https://www.tga.gov.au

For access to this leaflet, please visit: https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

Sponsor

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